REMARKS

Claims 1-31 are pending. Claims 17-30 are withdrawn.

Claim Rejections

The Examiner has rejected Claims 1-16 and 31 under 35 USC §103(a) as being unpatentable over Kamath et al. ("Kamath") (6,335,029) in view of Davidson (5,415,704).

The Examiner asserts that the material as claimed is "well known in the art for use in making a vascular implant (Paragraph 3, Office Action)." However, the Examiner has not provided any evidence to support the contention that a material for constructing a stent body which includes a metallic substance and a carbon deposit present at a molecular level within the metallic substance and at a depth within a surface of the stent as recited in Claim 1 of the invention. Applicants traverse the assertion that the material as claimed is well known in the art for use in making a vascular implant. MPEP §2144.03 states that, "the rationale for supporting an obviousness rejection may be based on common knowledge in the art or 'well-known' in the art." If an applicant traverses such an assertion, the Examiner is required to cite a reference in support of the office's position. If no such reference is provided, Applicants respectfully request that the claim rejections that are based on this assertion be removed. Moreover, Applicants respectfully request that this statement of facts outside of the record be expressly removed from the record.

Further, the Examiner asserts that Kamath discloses a base metallic material, but does not disclose a material for constructing a stent body which includes a metallic substance and a carbon deposit present at a molecular level within the metallic substance and at a depth within a surface of the stent as recited in Claim 1 of the invention. The Examiner concluded that the deficiency of Kamath is cured by Davidson, disclosing a metallic substance and a carbon deposit present at a molecular level within the metallic substance and at a depth within a surface of an implant to strengthen and harden an alloy surface for improved abrasion resistance for long term placement of an implant in a body. Therefore, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify or substitute the base metallic material

of Kamath with the metallic material as disclosed by Davidson to improve abrasion resistance for long term placement of the stent in a body.

Applicants traverse the rejection based on the following reasons:

1) It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Kamath and Davidson teach away from each other. Although Kamath teaches a metallic base material 3, Kamath also teaches depositing a **bioactive agent polymer composite layer(s) 5 on metal base layer 3** (Fig. 1, Col. 7, line 30-32). In addition to the composite layer(s) 5, a **plasma deposited barrier layer(s) 20 is deposited over the composite layer(s)**, having a thickness adequate to provide a controlled release of the bioactive material from the composite layer(s) (Col. 2, lines 40-54). Further, Kamath is geared toward **surface** deposition. In stark contrast, Davidson teaches "interstitial diffusion" strengthening with oxygen, nitrogen, and carbon **throughout** the material of the product. Col. 9, lines 61-64 of Davidson emphasizes the desire to eliminate an external oxide or nitride coating by stating, "[i]t should be noted that the internal oxidation and interstitial diffusion hardening methods can be controlled to **minimize or eliminate the formation of an external scale-type coating**." More specifically, Davidson teaches that oxygen, nitrogen, and carbon concentrations, "are kept sufficiently **low** so that there is **no significant formation of an external** oxide, nitride, or carbide scale so that an essential **metallic-type appearance remains on the surface**" (Col. 9, lines 40-44).

Simply put, Davidson specifically teaches **against formation of an "external" coating in its metal surface, while Kamath is specifically directed to "external" coating on its metal surface**. In fact, the essence and main objective of the Kamath invention is to form a barrier layer that forms covalent bonds with the agent-polymer composite layer to control drug delivery as well as protect the drug in the composite layer (Col. 7, lines 30-47, and Col 8, lines 37-44). Clearly, this is a classic example of two references teaching away from one another.

2. There is no motivation to combine Kamath and Davidson. Even though Davidson teaches that the process can be used with cardiovascular devices, Davidson fails to teach the use of stents, specifically. **Stents are not the type of cardiovascular**

devices that can be subjected to the case hardening treatment of Davidson. Davidson teaches increasing the surface hardness of the material **in excess of 60 Rockwell C** (Col. 9, line 46). Stents, as taught in Kamath, are deformable structures, subjected to bending, expanding, contracting, cyclic loading or similar stresses. **The application of the case hardening technique of Davidson to the stents of Kamath can lead to cracking of the stents under such stresses**. In the art, hardness of 60 Rockwell C is deemed unsuitable for Kamath's stent applications (See Dr. Kramer-Brown Declaration, paragraph 9).

Moreover, Davidson is directed to devices that need "surface abrasion resistance" improvement (Col. 9, line 25-27). **Davidson as a whole teaches devices that are prone to abrasion such as knee joints, hip prosthesis, compression screws and the like. Stents as taught in Kamath are not in contact with any surfaces that may pose the need of improving the surface abrasion resistance.** Rather, Kamath teaches providing a blood compatible surface to the medical Device. Thus, the biocompatible polymer material acts as an intermediary between the vascular walls or the blood stream and the implantable medical device (Col. 7, lines 16-21). Accordingly, one of ordinary skill in the art would not be motivated to improve the surface abrasion resistance properties of a stent. Thus, there is absolutely no motivation to use the process of Davidson in forming the stent of Kamath.

Furthermore, with respect to the dependent Claim 8, for example, the tissue-contacting surface of the stent is modified. Bearing in mind that the tissue with which a stent has contact is soft tissue, there is absolutely no need to make such surface resistant to abrasion.

Furthermore, with respect to the dependent Claims 3, 4, and 5, for example, the deposition of a polymer layer will make the surface more prone to abrasion and not less. Application of a polymer coating on the modified surface of Davidson would be counter-intuitive to the purpose of the Davidson invention.

Furthermore, with respect to dependent Claim 12, for example, the deposition of an organic film layer on the surface will make the surface of Davidson more prone to

abrasion and not less. Further, the film layer can not be chemically bonded to the metallic surface of Davidson as in Claim 12.

3. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). The combination of Davidson into Kamath renders Kamath unsatisfactory for its intended purpose. Enclosed is a declaration by Dr. Pamela Kramer-Brown, a PhD in material science, and one of ordinary skill of the art of stent material science, which clearly points to three reasons why the combination of Davidson into Kamath renders Kamath unsatisfactory for its intended purpose.

First, as indicated by the declaration, an alloy having hardness exceeding 60 Rockwell C as taught in Davidson can not be used in stents as in '449 because such hardness does not provide adequate flexibility in stents (Col. 9, line 44-48, Paragraph 9 of Declaration).

Further, the depth of hardness that Davidson refers to (100 microns or deeper as in tables) makes the product very stiff. Dr. Kramer-Brown provides that those skilled in the art understand that a harder material experiences less elongation, thereby making a balloon expandable stent susceptible to crack upon expansion (Paragraph 10 of Declaration).

Still further, Dr. Kramer-Brown provides that the precipitates in Davidson that are caused by hardening (whether with oxides, nitrides, or carbides) are undesirable for stent use from a strength perspective. For example, precipitates may act as crack initiation sites in high strain areas via 'fallout'. That is, precipitates on the stent surface are exposed during normal polishing of the stent. The precipitates then fall out from the stent when expanded, leaving a hole or crack at or within the surface of the stent (Paragraph 11 of Declaration.

Applicants respectfully ask that the rejection of independent Claim 1 and its dependent claims be removed. Similarly, Applicants ask that rejection of independent Claim 12 and its dependent claims also be removed for at least the same reasons stated

above. Since Claims 1-16 and 31 are in a condition for allowance, please issue a Notice of Allowability. Feel free to contact me if I can be of any assistance.

Respectfully submitted,

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